

ART SUBJECT

CLAIMS

What we claim is:

1. A multivalent immunogenic composition for conferring protection in a host against disease caused by infection by respiratory syncytial virus (RSV) and influenza virus, which comprises:

(a) an immunoeffective amount of a mixture of purified fusion (F) protein, attachment (G) protein and matrix (M) protein of RSV, and

(b) an immunoeffective amount of a non-virulent influenza virus preparation.

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said immunogenic composition of being formulated as a vaccine for *in vivo* administration to the host wherein the individual components (a) and (b) of the composition are formulated such that the immunogenicity of the individual components (a) and (b) is not impaired.

2. The immunogenic composition of claim 1 further comprising an adjuvant.

3. The immunogenic composition of claim 2 wherein said adjuvant imparts an enhanced immune response to RSV when compared to the mixture (a) formulated with the adjuvant in the absence of the non-virulent influenza virus preparation.

4. The immunogenic composition of claim 2 wherein the adjuvant is poly-di(carboxylatophenoxy)-phosphazene (PCPP).

5. The immunogenic composition of claim 1 wherein said mixture (a) is present in an amount of about 10 to about 200  $\mu$ g and (b) is present in an amount of about 1 to about 100  $\mu$ g in a single dose.

6. The immunogenic composition of claim 1 wherein said fusion (F) protein comprises multimeric fusion (F) proteins.

7. The immunogenic composition of claim 6 wherein, when analyzed under non-reducing conditions, said multimeric fusion (F) protein includes heterodimers of molecular weight approximately 70 kDa and dimeric and trimeric forms.

8. The immunogenic composition of claim 1 wherein, when analyzed under non-reducing conditions, said attachment (G) protein comprises G protein of molecular weight approximately 95 kDa and G protein of molecular weight approximately 55 kDa and oligomeric G protein.

9. The immunogenic composition of claim 1 wherein, when analyzed by SDS-PAGE under non-reducing conditions, said matrix (M) protein comprises M protein of molecular weight approximately 28 to 34 kDa.

10. The immunogenic composition of claim 1 wherein, when analyzed by reduced SDS-PAGE analysis, said fusion (F) protein comprises an F<sub>1</sub> subunit of molecular weight approximately 48 kDa and an F<sub>2</sub> subunit of molecular weight approximately 23 kDa, said attachment (G) protein comprises a G protein of molecular weight approximately 95 kDa and a G protein of molecular weight approximately 55 kDa, and said matrix (M) protein comprises an M protein of approximately 31 kDa.

11. The immunogenic composition of claim 1 wherein said F, G and M proteins are present in mixture (a) in the relative proportions of:

F from about 35 to about 70 wt%

G from about 5 to about 30 wt%

M from about 10 to about 50 wt%

12. The immunogenic composition of claim 11 wherein, when analyzed by SDS-PAGE under reducing conditions and silver stained, the ratio of F<sub>1</sub> subunit of molecular weight approximately 48 kDa to F<sub>2</sub> subunit of molecular weight approximately 23 kDa is between 1:1 to about 2:1 as determined by scanning densitometry.

13. The immunogenic composition of claim 12 wherein said mixture is at least about 75% pure.

14. The immunogenic composition of claim 1 wherein said RSV proteins in said mixture are from one or both of subtypes RSV A and RSV B.

15. The immunogenic composition of claim 1 wherein said non-virulent influenza virus preparation comprises a plurality of different non-virulent influenza virus strains.

16. The immunogenic composition of claim 15 wherein said non-virulent influenza virus preparation is an inactivated influenza virus preparation.

17. The immunogenic composition of claim 15 wherein said non-virulent influenza virus preparation comprises an attenuated influenza virus.

18. The immunogenic composition of claim 1 wherein said non-virulent influenza virus preparation comprises at least one influenza antigen.

19. The immunogenic composition of claim 1 when used as a vaccine.

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20. A method of immunizing a human host against disease caused by infection by respiratory syncytial virus (RSV) and by influenza virus, which comprises administering to the host an immunoeffective amount of the immunogenic composition of claim 1.

21. The method of claim 20 wherein said host is a human host of at least 18 years of age.

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